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PTO/SB/21 (08-00)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

1636  
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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number 09/359,975

Filing Date July 23, 1999

First Named Inventor David B. Weiner

Group Art Unit 1636

Examiner Name D. Guzo

Total Number of Pages in This Submission

Attorney Docket Number UPAP0002-100 (F-983)

### ENCLOSURES (check all that apply)

☐ Fee Transmittal Form

☐ Fee Attached

☐ Amendment / Response

☐ After Final

☐ Affidavits/declaration(s)

☐ Extension of Time Request

☐ Express Abandonment Request

☒ Supplemental Information  
Disclosure Statement

☐ Certified Copy of Priority  
Document(s)

☐ Response to Missing Parts/  
Incomplete Application

☐ Response to Missing  
Parts under 37 CFR  
1.52 or 1.53

☐ Assignment Papers  
(for an Application)

☐ Drawing(s)

☐ Licensing-related Papers

☐ Petition

☐ Petition to Convert to a  
Provisional Application

☐ Power of Attorney, Revocation  
Change of Correspondence Address

☐ Terminal Disclaimer

☐ Request for Refund

☐ CD, Number of CD(s) \_\_\_\_\_

☐ After Allowance Communication to  
Group

☐ Appeal Communication to Board of  
Appeals and Interferences

☐ Appeal Communication to Group  
(Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Other Enclosure(s)  
(please identify below):

Form PTO/SB/08a and  
PTO/SB/08b (2 pp.); (43) 10  
References Cited and Copies of  
(3) Cited References Enclosed;  
European Search Report Dated  
October 21, 2004 for EP  
Application No. 04 07 5092.

Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm  
or  
Individual name

Mark DeLuca, Registration No. 33,229

Signature

Date

11/18/04

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UPAP0002-100 (F-983)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **David B. Weiner et al.**

Serial No.: **09/359,975**

Group Art Unit: **1636**

Filing Date: **July 23, 1999**

Examiner: **D. Guzo**

For: **Compositions And Methods For Delivery Of Genetic Material**

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On November 18, 2004

Mark DeLuca, Registration No. 33,229

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08a and PTO Form SB/08b, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Supplemental Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☐ **before** the mailing date of a first Office Action on the merits.
- ☒ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
  - ☒ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), (see "Statement," and "Fees" below).
- ☒ Copies of the reference listed on the attached PTO Form SB/08a and PTO Form SB/08b, formerly known as PTO Form 1449 is enclosed. Also enclosed is a copy of the European Search Report Dated October 21, 2004 for Application No: EP 04 07 5092.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of reference @@@, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☒ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement; or that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☐ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,

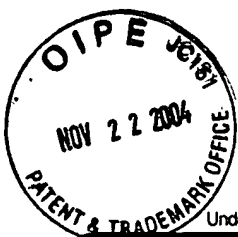


Mark DeLuca.  
Registration No. 33,229

Dated: November 18, 2004

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

**Complete if Known**

Application Number	09/359,975
Filing Date	July 23, 1999
First Named Inventor	David B. Weiner
Art Unit	1636
Examiner Name	D. Guzo
Attorney Docket Number	UPAP0002-100 (F-983)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		THOMASON et al., "Stable Incorporation Of A Bacterial Gene Into Adult Rat Skeletal Muscle In-Vivo," <i>American Journal Of Physiology</i> , 1990, Vol. 258, No. 3, pp. C578-C582.	
		DE-CHU et al., "Genetic Immunization In A Simple Method For Eliciting An Immune Response," <i>Nature</i> , 1992, Vol. 356, No. 6365, pp. 152-154.	
		KANEDA et al., "Increased Expression Of DNA Cointroduced With Nuclear Protein In Adult Rat Liver," <i>Science</i> , 1989, Vol. 243, pp. 375-378.	
		WANG et al., "Gene Inoculation Generates Immune Responses Against Human Immunodeficiency Virus Type 1," <i>Proceedings Of The National Academy Of Sciences</i> , 1993, Vol. 90, No. 9, pp. 4156-4160.	
		WELLS et al., "Improved Gene Transfer By Direct Plasmid Injection Associated With Regeneration In Mouse Skeletal Muscle," <i>FEBS Letters</i> , 1993, Vol. 332, No. 1/2, pp. 179-182.	
		European Search Report dated October 21, 2004 for European Application No. 04 07 5092	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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